

Beyond Air® Reports Financial Results for the First Quarter of Fiscal Year 2022

U.S. FDA reviewing premarket approval (PMA) submission for LungFit® PH to treat persistent pulmonary hypertension of the newborn (PPHN); On track for commercial launch in the fourth quarter of calendar year 2021

Anticipate reporting interim results from the LungFit® GO Nontuberculous Mycobacteria (NTM) lung infection at-home pilot study (self-administration) in Fall 2021

Positive data presented at American Thoracic Society in May 2021 from acute viral pneumonia (including COVID-19) study using LungFit® PRO at 150 ppm NO

Solid tumor program expected to receive regulatory clearance to initiate first in human studies by the end of calendar year 2021

Conference call scheduled for today, August 10th, at 4:30 p.m. ET

GARDEN CITY, N.Y., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Beyond Air, Inc. (NASDAQ: XAIR), a clinical-stage medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and gaseous NO (gNO) for the treatment of solid tumors, today announced financial results for its first fiscal quarter ended June 30, 2021.

"Our commercial team is ready to introduce the LungFit® PH system to hospitals across the United States, with FDA approval anticipated to be received at the end of next month. I am confident in our ability to successfully bring to market what will be the first-ever FDA approved generator and delivery system that produces NO from ambient air. LungFit® PH is designed to offer a simple, safe, cost effective and convenient alternative to the NO delivery systems that are currently available to treat PPHN," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "We are making progress in our other programs and anticipate reporting interim data from our at-home NTM pilot study using LungFit® GO in the fall. Our LungFit® PRO acute viral pneumonia study in adults, which includes COVID-19 patients, remains open and we expect to discuss our progress with FDA this fall in order to plan next steps. We also expect to receive regulatory clearance to start human studies in our solid tumor program using ultra-high concentration gNO around the end of calendar year 2021 and begin enrolling patients in early 2022."

Duncan Fatkin, Chief Commercial Officer of Beyond Air, stated, "Our initial commercial launch team is in place with experienced leaders to head our sales and marketing efforts in the US, and our partnership efforts internationally. We established our supply chain well in advance and are now in the process of finalizing our marketing plan. As we get closer to the

anticipated approval date, we are increasingly excited to fulfill Beyond Air's vision of harnessing the power of nitric oxide to transform the lives of patients."

Recent Highlights and Upcoming Milestones

- **LungFit® PH**

- FDA review of the PMA to treat PPHN is ongoing
- Commercial launch in the United States planned for the fourth quarter of calendar year 2021
- Expect to secure CE Mark in the European Union around the end of calendar year 2021; followed by ex-U.S. commercial partnership in 2022

- **LungFit® PRO**

Acute Viral Pneumonia Data

- Initiated a pilot study for acute viral pneumonia in adults, including COVID-19 patients, in Israel using LungFit® PRO at 150 ppm NO; patient enrollment began in November 2020 and is ongoing

Upcoming Study (pending discussions with FDA in Fall 2021)

- Plan on initiating a pivotal trial for patients hospitalized with viral lung infections, either for acute viral pneumonia or bronchiolitis, in the fourth quarter of calendar year 2022

- **LungFit® GO**

- Initiated an at-home pilot study in Australia using LungFit® GO for self-administration of up to 250 ppm NO for the treatment of refractory NTM lung disease in adult patients
- Expect to report interim data for the at-home NTM lung infection pilot study at a medical or scientific conference in Fall 2021 with the trial completing in the first half of calendar year 2022

- **Solid Tumor Program**

- Anticipate receiving regulatory clearance to initiate human studies around the end of calendar year 2021
- Anticipate beginning the enrollment of patients in the first quarter of calendar year 2022

Financial results for the fiscal quarter ended June 30, 2021

Revenue for the fiscal quarter ended June 30, 2021 was \$0 as compared to \$229,000 for the fiscal quarter ended June 30, 2020, all of which was licensing revenue.

Research and development expenses for the fiscal quarter ended June 30, 2021 were \$2.7 million, compared to \$4.3 million for the fiscal quarter ended June 30, 2020.

General and administrative expenses for the fiscal quarter ended June 30, 2021 were \$3.9 million, compared to \$2.5 million for the fiscal quarter ended June 30, 2020.

For the fiscal quarter ended June 30, 2021, the Company had a net loss of \$6.7 million, or (\$0.31) per share, compared to a net loss of \$6.7 million, or (\$0.41) per share for the fiscal quarter ended June 30, 2020.

As of June 30, 2021, the Company had cash, cash equivalents and restricted cash of \$39.6 million.

Conference Call & Webcast

Tuesday, August 10th @ 4:30 PM ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13721640

Webcast: <http://public.viavid.com/index.php?id=145783> or the Events page of the Company's website

About Beyond Air, Inc.

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System, LungFit®, that uses NO generated from ambient air to deliver precise amounts of NO to the lungs for the potential treatment of a variety of pulmonary diseases. The LungFit® can generate up to 400 ppm of NO, for delivery either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. The Company is currently applying its therapeutic expertise to develop treatments for pulmonary hypertension in various settings, in addition to treatments for respiratory tract infections that are not effectively addressed with current standards of care. Beyond Air is currently advancing its revolutionary LungFit® for clinical trials for the treatment of severe lung infections such as acute viral pneumonia (including COVID-19) and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is using ultra-high concentrations of NO with a proprietary delivery system to target certain solid tumors in the pre-clinical setting. For more information, visit www.beyondair.net.

About Nitric Oxide (NO)

Nitric Oxide (NO) is a powerful molecule, naturally synthesized in the human body, proven to play a critical role in a broad array of biological functions. In the airways, NO targets the vascular smooth muscle cells that surround the small resistance arteries in the lungs. Currently, exogenous inhaled NO is used in adult respiratory distress syndrome, post certain cardiac surgeries, and persistent pulmonary hypertension of the newborn to treat hypoxemia. Additionally, NO is believed to play a key role in the innate immune system and in vitro studies suggest that NO possesses anti-microbial activity not only against common bacteria, including both gram-positive and gram-negative, but also against other diverse pathogens, including mycobacteria, viruses, fungi, yeast, and parasites, and has the potential to eliminate multi-drug resistant strains.

About the LungFit®*

Beyond Air's LungFit® is a cylinder-free, phasic flow nitric oxide generator and delivery system and has been designated as a medical device by the U.S. Food and Drug Administration (FDA). The ventilator compatible version of the device can generate NO from ambient air on demand for delivery to the lungs at concentrations ranging from 1 part per million (ppm) to 80 ppm. The LungFit® system could potentially replace large, high-pressure NO cylinders providing significant advantages in the hospital setting, including greatly

reducing inventory and storage requirements, improving overall safety with the elimination of NO₂ purging steps, and other benefits. The LungFit® can also deliver NO at concentrations at or above 80 ppm for potentially treating severe acute lung infections in the hospital setting (e.g. COVID-19, bronchiolitis) and chronic, refractory lung infections in the home setting (e.g. NTM). With the elimination of cylinders, Beyond Air intends to offer NO treatment in the home setting.

* *Beyond Air's LungFit® is not approved for commercial use. Beyond Air's LungFit® is for investigational use only. Beyond Air is not suggesting NO use over 80 ppm or use at home.*

About PPHN

Persistent pulmonary hypertension of the newborn (PPHN) is a lethal condition and secondary to failure of normal circulatory transition at birth. It is a syndrome characterized by elevated pulmonary vascular resistance (PVR) that causes labile hypoxemia due to decreased pulmonary blood flow and right-to-left shunting of blood. Its incidence has been reported as 1.9 per 1000 live births (0.4–6.8/1000 live births) with mortality rate ranging between 4–33%. This syndrome complicates the course of about 10% of infants with respiratory failure and remains a source of considerable morbidity and mortality. NO gas is a vasodilator, is approved in dozens of countries to improve oxygenation and reduces the need for extracorporeal membrane oxygenation (ECMO) in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

About Acute Viral Pneumonia

In adults, viruses have been identified as the causative agents in approximately 100 million cases of community-acquired pneumonia per year. While viral pneumonia in adults is most commonly caused by rhinovirus, respiratory syncytial virus (RSV) and influenza virus, newly emerging viruses (including SARS-CoV-1, SARS-CoV-2, avian influenza A, and H1N1 viruses) have been identified as pathogens contributing to the overall burden of adult viral pneumonia. Patients aged 65 years or older are at particular risk for death from the disease, as are patients with other underlying health conditions or weakened immune systems. There is no consensus regarding the use of antiviral drugs to treat viral pneumonia, and specific preventative measures are currently limited to the influenza vaccine. Given that current treatment recommendations are largely limited to supportive care, there is an unmet medical need for effective treatment options.

About NTM

Nontuberculous mycobacteria (NTM) is a rare and serious bacterial infection in the lungs causing debilitating pulmonary disease associated with increased morbidity and mortality. NTM infection is acquired by breathing in aerosolized bacteria from the environment, and if ignored can lead to NTM lung disease, a progressive and chronic condition. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics delivered continually for as long as two years. These complex, expensive and invasive regimens have a poor record in the treatment of *Mycobacterium abscessus* complex (MABC) and refractory *Mycobacterium avium* complex (MAC) and have the potential for causing severe adverse events. Beyond Air's system is designed to effectively deliver 150 - 400 ppm NO to the lung, and early data indicate that this range of NO concentration may have a positive

effect on patients infected with NTM.

About Bronchiolitis

The majority of hospital admissions of infants with bronchiolitis are caused by respiratory syncytial virus (RSV). RSV is a common and highly transmissible virus that infects the respiratory tract of most children before their second birthday. While most infants with RSV present with minor respiratory symptoms, a small percentage develop serious lower airway infections, termed bronchiolitis, which can become life-threatening. The absence of treatment options for bronchiolitis limits the care of these sick infants to largely supportive measures. Beyond Air's system is designed to effectively deliver 150 - 400 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi, and other microbes from the lungs.

About Solid Tumors

Cancer is the second leading cause of death globally, with tumor metastases responsible for approximately 90% of all cancer-related deaths. Current cancer treatment modalities generally include chemotherapy, immunotherapy, radiation, and/or surgery. Nitric oxide at ultra-high concentrations has been reported to show anticancer properties and to serve as a chemosensitizer and radiotherapy enhancer. Based on its current findings, Beyond Air is developing treatment protocols using ultra-high nitric oxide concentrations to ablate primary tumors and treat metastatic disease.

Forward Looking Statements

This press release contains "forward-looking statements" concerning inhaled nitric-oxide and the Company's LungFit® product, including statements with regard to potential regulatory developments, the potential impact on patients and anticipated benefits associated with its use. Forward-looking statements include statements about our expectations, beliefs, or intentions regarding our product offerings, business, financial condition, results of operations, strategies, or prospects. You can identify such forward-looking statements by the words "anticipates," "expects," "intends," "impacts," "plans," "projects," "believes," "estimates," "likely," "goal," "assumes," "targets" and similar expressions and/or the use of future tense or conditional constructions (such as "will," "may," "could," "should" and the like) and by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including risks related to: our approach to discover and develop novel drugs, which is unproven and may never lead to efficacious or marketable products; our ability to fund and the results of further pre-clinical and clinical trials; obtaining, maintaining and protecting intellectual property utilized by our products; our ability to enforce our patents against infringers and to defend our patent portfolio against challenges from third parties; our ability to obtain additional funding to support our business activities; our dependence on third parties for development, manufacture, marketing, sales, and distribution of products; the successful development of our product candidates, all of which are in early stages of

development; obtaining regulatory approval for products; competition from others using technology similar to ours and others developing products for similar uses; our dependence on collaborators; our short operating history and other risks identified and described in more detail in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on our website. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements, except as required by applicable law.

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BEYOND AIR, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2021	March 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 38,581,386	\$ 34,630,682
Restricted cash	1,046,606	637,025
Grant receivable	-	425,000
Other current assets and prepaid expenses	1,325,064	1,530,096
Total current assets	<u>40,953,056</u>	<u>37,222,803</u>
Licensed right to use technology	365,158	374,686
Right-of-use lease assets	1,815,351	1,860,885
Property and equipment, net	897,550	928,842
Other assets	137,880	137,880
TOTAL ASSETS	\$ 44,168,995	\$ 40,525,096
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities		
Accounts payable	\$ 2,261,777	\$ 1,324,988
Accrued expenses	1,695,235	1,804,938
Operating lease liability	187,288	113,141
Loan payable	349,165	556,514
Total current liabilities	4,493,464	3,799,581

Long-term liabilities		
Operating lease liability	1,720,389	1,789,461
Long-term debt, net	4,505,393	4,472,201
Total liabilities	<u>10,719,247</u>	<u>10,061,243</u>
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, \$0.0001 par value per share: 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common Stock, \$0.0001 par value per share: 100,000,000 shares authorized, 23,267,649 and 21,828,244 shares issued and outstanding as of June 30, 2021 and March 31, 2021, respectively	2,327	2,183
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	120,677,112	110,948,477
Accumulated deficit	(87,204,691)	(80,461,807)
Total stockholders' equity	<u>33,449,748</u>	<u>30,463,853</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 44,168,995	40,525,096

BEYOND AIR, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended June 30,	
	2021	2020
License revenue	\$ -	<u>229,161</u>
Operating expenses		
Research and development	2,741,041	4,331,814
General and administrative	<u>3,850,265</u>	<u>2,494,014</u>
Operating loss	<u>(6,591,306)</u>	<u>(6,596,667)</u>
Other income (loss)		
Dividend income	706	14,985
Foreign exchange gain	9,859	1,275
Interest expense	(162,143)	(163,240)
Other	-	1,843

Total other loss	<u>(151,578)</u>	<u>(145,137)</u>
Net loss	\$ (6,742,884)	\$ (6,741,804)
Net loss per share – basic and diluted	\$ (0.31)	\$ (0.41)
Weighted average number of common shares outstanding – basic and diluted	21,945,235	16,529,392



Source: Beyond Air™